

### Support for Amended Claims

To provide additional clarity to the claim text, amendments to claims 1-3, 5-6, 8-17, 19-36, 39-50, and 57-59 include changes to antecedents, punctuation marks, and/or claim language. Unless otherwise noted below, these changes do not have an effect on claim scope. In claims 1, 17, 23, 32, 33, and 58, the term "cervix" has been replaced with the term "exocervix" to bring the language of these claims into conformity with other parts of the respective claims or, in the case of claim 32, with the language of the claim upon which it depends (claim 28). In claims 11, 14, and 19, the term "rim" has been replaced with "rim member" to bring these claims into conformity with the claims from which they, respectively, depend.

In claim 25, the text "and replaceable" has been added to the claim. Support for this amendment is found in the application on page 4, lines 15-16.

In claims 33, 34, and 57 the term "in combination" has been removed from the text of the claim. Support for this change is found in the application on page 6, lines 4-11, where this limitation does not appear.

Support for new claims 60 and 61 can be found in the application on page 10, lines 24-29.

### Remarks

#### *Claim Rejections 35 U.S.C. § 103(a)*

Examiner has rejected claims 1-3, 6, 10-11, 44-46, and 58-59 under 35 U.S.C. 103(a) as being unpatentable over Lipfert in view of Goepp. In addition, Examiner has rejected claim 5 under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 2 above, and further in view of Cox (U.S. Patent No. 5,065,772); claims 8-9, 12-13, 15, 17, 20, 22-25, 27, 41-43, and 47-48 under 35 U.S.C. 103(a) as being unpatentable over Lipfert in view of Goepp, along with Shields (U.S Patent No. 5,044,376); and Claims 16 and 21 under 35 U.S.C. 103(a) as being unpatentable over the references as applied to the claims above, and further in view of Petrus. These rejections are respectfully traversed.

The instant claims are to a cervical cap that comprises a rim member or to methods in which such a cap is used. The prior art does not describe a rim member in this context.

Pending claims 1-3, 5-6, 8-17, 19-22, 41-50, and 58-59 of the present application claim a cervical cap comprising a rim member (element **10** in the application) and a cap dome (element **34** in the application). Pending claims 23-27 are method claims using a cervical cap that includes a rim member and a cap dome. The term "rim member" is not the result of a capricious use of language and is meant in the claims to convey a distinctive element of the cervical cap of the present invention. Figure 1 provides a detailed drawing of rim member as an individual component, the description for which can be found in the specification on page 9, lines 6-17. Figure 3 illustrates rim member and cap dome as separate elements that have been fused together to form the cervical cap of the present invention, as described in the specification on page 10, lines 18-19, which reads: "Cap **32** comprises rim **10**, and dome **34** of biocompatible material bonded to surface **16** of rim **10**." In another example, the cervical cap of the present invention allows for the use of different materials for the construction of rim member and cap dome, respectively, as described on page 10, lines 24-29. The distinctive nature of rim member and cap dome are further exemplified in the description of the manufacture of the cervical cap of the present application on page 11, line 19, through page 12, line 28, in which rim member is fitted to the exocervix of a patient, a shell is fitted to the rim member, and a cap dome is formed by introducing a curable material to the inside of the shell, which cures and fuses to the rim member to form the cervical cap of the pending claims.

Lipfert et al., in U.S. Patent No. 3,952,737 (the '737 patent), disclose a cervical cap device that is molded from one piece of material. The cap includes lip portion **44** and inner bead sealing ring **46**. [Note: bolded numbers used in the remarks section correspond to those element numbers used in the document under discussion] After the Lipfert cap is initially fitted to a patient's cervix uteri, O-ring **30** may be moved from a first position to a second position, provided by positioning means **40**, to achieve the desired fit of this device to the cervix. The use of a cured polymeric material, the ability to custom fit this device to a patient's cervix, or the use of a rim element in the construction of the cap is not described or suggested in the '737 patent.

Goepp et al., in U.S. Patent Nos. 4,363,318 (the '318 patent) and in 4,543,949 (the '949 patent), disclose a cervical cap that is fabricated from elastomeric material using a replica of a patient's cervix uteri as a mold. Goepp et al., in U.S. Patent No. 4,517,970 (the '970 patent), also describe a custom formed cervical cap that includes outer (away

from the uterus) shell 30, inner liner sheath 44, which makes intimate contact with the cervix uteri during the molding process, and elastomeric layer 36, which is intermediate between shell 30 and sheath 44 after its introduction before or during an *in situ* molding process. After molding and curing is complete, the form is removed from the patient and sheath 44 is removed from cured elastomeric layer 36 to provide a custom-fitted cervical cap. The '970 patent discloses several rim possibilities (rim 42, rim 42, rim 142, rim 242, rim 442, and rim 942), each relating to the rim of either the device shell or the liner sheath. A component rim member for the Goepp cervical cap is not described or suggested in any of the '318, '949, or '970 patents.

Examiner argues that "Lipfert discloses in figures 1-3 a cervical cap comprising a rim member (30, 44) dimensioned to fit a patient's cervix..." [emphasis added]. The Examiner's characterization of Lipfert is incorrect: the cervical cap of Lipfert does not include a rim member. The device disclosed by Lipfert is of one-piece construction and contains a rim, as would any other concave or convex object. Examiner correctly notes that "Lipfert does not disclose the cap dome being made of a cured polymeric material or the cap dome being custom made." Examiner also correctly notes that "Goepp teaches in figure 1 a custom made cap dome comprising a rim 35 that permits a snug fit between rim 35 and the exocervix. The cap dome is made of a cured polymeric material." Examiner then argues that "it would have been obvious to one skilled in the art at the time that the invention was made that the cap dome as disclosed by Lipfert could be fabricated on a cured polymeric material as taught by Goepp" and that the "teaching of a rim that snugly fits the exocervix is clearly provided by Goepp." Examiner does not take into account the significant differences between the cervical cap of the Koch application and the teachings of Lipfert or Goepp, neither of which describe a rim member and dome elements as separate elements.

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination [see *In re Napier*, 55 F.3d 610, 613, 34 U.S.P.Q.2d 1782 1784 (Fed. Cir. 1995)]. The Federal Circuit has also opined in *In re Mills*, 916 F.2d.680 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990) that "[it] is not pertinent whether the prior art device possesses the functional characteristics of the claimed device if the reference does not describe or suggest its structure." Citing *In re Grodon*,

733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984) the Federal circuit pointed out that "while [the prior art] apparatus may be capable of being modified to run the way [Applicant's] apparatus is claimed, there must be a suggestion or motivation in the reference to do so."

Examiner has provided no evidence of any suggestion or motivation in the cited art that would lead to the cervical cap claimed in the present application. Furthermore, even if combined, the teachings of Lipfert and Goepp would not produce the presently claimed cervical cap.

In view of the argument presented above regarding the 103(a) rejection of 1-3, 6, 10-11, 44-46, and 58-59 over Lipfert in view of Goepp, Applicant submits that claim 5; claims 8-9, 12-13, 15, 17, 20, 22-25, 27, 41-43, and 47-48; and claims 16 and 21 are also patentable over Lipfert, Goepp and the additional references cited by examiner (Cox, Shields, and Petrus, respectively).

*Claim Rejections 35 U.S.C. § 102(b)*

Examiner has rejected claims 33-36, 39-40, and 51 under 35 U.S.C. 102(b) as being clearly anticipated by Goepp.

In the present Office Action, Examiner has responded to the detailed arguments contained in Applicant's reply of June 19, 2003 by simply repeating the previous rejection verbatim, including the rejection of claim 51, which was cancelled in Applicant's reply of January 23, 2003 and whose cancelled status was maintained in Applicant's reply of June 19, 2003, as then noted. Other than a recitation of the 35 U.S.C. § 102(b) statute, Examiner's only guidance in this matter is that pending claims 33-36, 39-40, and 51 are "clearly anticipated by Goepp." Applicant respectfully traverses this rejection. Every limitation of the kits of the rejected claims is not described by Goepp.

Goepp does not teach a kit that includes a rim member with a substantially ring-shaped surface dimensioned to fit a patient's exocervix, which when placed on the exocervix faces toward the opening of the patient's vagina, and means for applying a curable material to the ring shaped surface of the ring member (claim 33 of the present application). Nor does Goepp teach or suggest a kit including a rim member dimensioned to fit an exocervix, and a shell member dimensioned to be mounted on the rim member (claim 34 of the present application). Instead,

Goepp teaches forming a cap by placing the hollow cup 67 of an impression tray 65 over the cervix, and injecting a hardenable paste into the hollow cup using a syringe. While the hollow cup 67 has a lip 69, this lip is integral with the cup. It is not a rim member. Nor does it define a ring-shaped surface that faces toward the opening of the patient's vagina and to which curable material is applied. With regard to claim 34, clearly the lip of the cup cannot be construed as a rim member onto which a shell can be mounted. Thus, Goepp cannot anticipate claim 33 or 34. Claims 35-36 and 39-40 depend directly or indirectly from claim 34 and thus are patentable for at least the same reasons.

Summary

In view of the above remarks, Applicant submits that all claims are in form for allowance and respectfully requests that Examiner withdraw the rejections under §§ 103(a) and 102(b).

Effective immediately, please forward all correspondence relating to the above-captioned application to:


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Enclosed is a Petition to extend the period for replying to the Office action for two months, to and including February 25, 2004 and a check for \$210.00 in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: Feb 25, 2004

  
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